

**VIRGINIA DEPARTMENT OF HEALTH
RADIOLOGICAL HEALTH**

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**IN VIRO TESTING WITH RADIOACTIVE MATERIAL UNDER A GENERAL LICENSE
CONDITIONS AND LIMITATIONS OF GENERAL LICENSE § 4.22-I**

§ 4.22-I-1. General license for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.

1. A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of § 4.22-I-2, 3, 4, 5, and 6, the following radioactive materials in prepackaged units for use in vitro, clinical or laboratory test not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
 - a. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
 - b. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by § 4.22-I-1 until he has filed Agency Form RH-F-14, "Certificate" – In Vitro Testing with Radioactive Material Under General License", with the commissioner and received from the commissioner a validated copy of Agency Form RH-F-14 with certification number assigned, or until he has been authorized pursuant to § 4.26-C-3 to use radioactive material under the general license of § 4.22-I. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form RH-F-14 the following information and such other information as may be required that form:
 - a. Name and address of the physician, veterinarian, clinical laboratory or hospital ;
 - b. The location of use; and
 - c. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in § 4.22-I-1 and that such tests will be performed only by personnel competent in the use of such instruments and the handling of radioactive material.
3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by § 4.22-I-1 Shall comply with the following:
 - a. The general licensee shall not possess at any one time, pursuant to the general license in § 4.22-I-1, at any one location of Iodine-125 and/or iodine-131 in excess of 200 microcuries (7.4 MBq).
 - b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container Providing equivalent radiation protection.
 - c. The general licensee shall use the radioactive material only for the uses authorized by § 4.22-I-1.
 - d. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the commissioner, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
4. The general licensee shall not receive, acquire, possess or use radioactive material pursuant to § 4.22-I-1:
 - a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued Pursuant to § 4.28-H or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacturers and distribution of iodine-125 or iodine-131 to persons generally licensed under § 4.22-I or it's equivalent, and
 - b. unless one of the following statements, as appropriate, or substantially similar statement which contains the information called for in one of the statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
 - (1) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material , or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of Manufacturer

- (2) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro tests not involving internal or external administration of the material, or radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of Manufacturer

5. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license Of § 4.22-I-1 shall report in writing to the commissioner, any changes in the information furnished by him in the "Certificate" – In Vitro Testing with Radioactive Material Under General License", Agency Form RH-F-14. The report shall be furnished within 30 days after the effective date of such change.
6. Any person using radioactive material pursuant to the general license of § 4.22-I-1 is exempt from the requirements of Part V and Part IX of these regulations with respect to radioactive material covered by that general license.

Note: If larger quantities or other forms of radioactive material than those specified in the general license of § 4.22-I are required, the physician should file an "application for Radioactive Material License", Agency Form RH-F-4 and obtain a specific radioactive material license. Copies of the application and certification forms may be obtained from: Va. Health Dept., Radiological Health, P.O. Box 2448, Richmond, Va. 23219.